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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,302	12/22/2005	Maria Torpo	P05,0367	3792

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EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,302	TORPO ET AL.	
	Examiner	Art Unit	
	Luther G. Behringer	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the communication received on 05/18/2009 concerning application no. 10/562302 filed on 12/22/2005.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/18/2009 has been entered.

Response to Amendment

3. The declaration filed on 02/20/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Salo et al. (US 2005/0102002) reference.

4. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Salo et al. (US 2005/0102002) reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). For a declaration under 37 CFR 1.131 to be

effective, it must show support for each and every claim. The declaration as filed 02/20/2009 fails to provide support for "a time duration of a predetermined phase of diastole of the heart" among other elements in claims 27, 47 and 48. One of ordinary skill, upon reading the reference, would not have been able to draft the claims of the instant application, those claims being narrower than the declaration.

5. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Salo et al. (US 2005/0102002) reference to either a constructive reduction to practice or an actual reduction to practice. In the instant application, applicant must provide diligence for the span of time between 09/17/2003 and 11/07/2003. Any showing of conception must be coupled with an establishment of diligence to effect an antedating of the claims of the instant application.

6. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Salo et al. (US 2005/0102002) reference. The claim language as filed is directed a narrower in scope application of the concept as illustrated in the declaration filed 02/20/2009 and, as such, illustrates the necessary further reduction to practice for the claimed invention.

7. As there is no showing supporting that the declaration as filed 02/20/2009 was a confidential or internal document, the examiner is treating it as prior art under 35 USC 102(b).

Response to Arguments

8. Applicant's arguments filed 05/18/2009 have been fully considered but they are not persuasive. As the Salo reference does provide for electrical therapy for diastolic dysfunction, it does provide an anticipating disclosure. Salo is consistently concerned with timing various parameters to determine time constants and whether measured physiological signals are in line with those time constants (See [0029, 0032, 0033]). Inherency, as applied to Salo, does not rely upon probabilities or possibilities as alleged by applicant. A careful reading of the cited portions of Salo will reveal the features as claimed, be it thresholds as applicable to claim(s) 28 and 49 or extrapolating mitral blood flow velocity to zero utilizing time constants of a decrease in blood flow as in claim(s) 30 and 51.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claim(s) 27 – 63 are rejected under 35 U.S.C. 102(b) as being anticipated by the **Invention Disclosure dated 09/17/2003** as provided applicant in a 37 CFR 1.131 declaration on 02/20/2009.

Applicant states that the Invention Disclosure filed 02/20/2009 provides sufficient support to antedate the instant application. Therefore the Invention Disclosure anticipates claim(s) 27 – 63 of the instant application.

12. Claim(s) 27 – 43 and 48 – 63 are rejected under 35 U.S.C. 102(e) as being anticipated by **Salo et al. (US 2005/0102002, herein Salo)**.

Applicant defines diastolic heart failure as an abnormality in the diastolic function (See page 1 of specification under background). The examiner is interpreting diastolic dysfunction as an equivalent term to abnormal diastolic function.

With regard to **claim(s) 27 and 48,** Salo discloses a method and an implantable medical apparatus for detecting diastolic heart failure (DHF) comprising: a sensor adapted to interact with a heart to obtain information associated with functioning of the heart; and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration of a predetermined phase of diastole of the heart, *diastolic performance parameter* [0027] and, upon detecting said DHF state, that emits an output signal indicating said DHF state, *diastolic performance based feedback loop* [0033].

Regarding **claim(s) 28 and 49,** Salo discloses wherein said DHF determining device comprises a comparator, *pacing parameter optimization module* **124**, that compares said time duration, *diastolic performance parameter*, with an upper limit value and a lower limit value to obtain a comparison result, said comparison result being indicative of said DHF state (Fig. 1B; [0031]).

With regard to **claim(s) 29 and 50,** Salo discloses wherein said DHF determining device comprises a calculating unit that calculates, from said information from said sensor, said time duration, as a time from an occurrence of peak blood flow velocity through the mitral valve of the heart to a time of occurrence of zero blood flow velocity through the mitral valve of the heart [0035].

Regarding **claim(s) 30 and 51,** Salo inherently discloses wherein said calculating unit determines said time duration by extrapolating said mitral blood flow velocity to zero, if an actual occurrence of zero blood flow velocity through the mitral valve does not occur before an atrial contraction of the heart [0029].

With regard to **claim(s) 31 and 52,** Salo inherently discloses wherein said calculating unit extrapolates the blood flow velocity to zero by determining a time derivative of blood flow velocity through the mitral valve shortly after said occurrence of said peak blood flow velocity through the mitral valve [0029].

Regarding **claim(s) 32 and 53,** Salo inherently discloses wherein said sensor senses an IEGM signal from the heart [0025], and wherein said calculating unit calculates the time of occurrence of said peak blood flow velocity through the mitral valve to the time of occurrence of zero blood flow velocity through the mitral valve from said IEGM [0035].

With regard to **claim(s) 33 and 54,** Salo discloses wherein said sensor is an impedance sensor that senses an impedance of the heart, *measure LV volume*, and wherein said calculating unit calculates the time from the occurrence of said peak blood

flow velocity through the mitral valve to zero blood flow velocity through the mitral valve from said impedance [0029].

Regarding **claim(s) 36 and 57,** Salo discloses wherein said DHF determining device comprises a calculating unit that calculates, as said time duration, an isovolumic relaxation time (IVRT) from said information from said sensor, *time constant (tau) related to a decreas in the left ventricular pressure* [0027].

With regard to **claim(s) 37 and 58,** Salo discloses wherein said sensor detects an IEGM from the heart [0025], and inherently discloses wherein said calculating unit determines said IVRT from said IEGM [0031].

Regarding **claim(s) 38 and 59,** Salo discloses wherein said sensor is an impedance sensor that measures an impedance of the heart [0029], and inherently wherein said calculating unit calculates said IVRT from said impedance [0031].

With regard to **claim(s) 41 and 62,** Salo inherently discloses wherein said DHF determining device determines said time duration, respectively at predetermined time intervals, thereby obtaining a plurality of time durations, *diastolic performance feedback loop*, and comprises a memory in which said plurality of time durations are stored, *therapy history data* [0032 – 0033].

Regarding **claim 42,** Salo discloses wherein said DHF determining device determines said time duration respectively at a plurality of predetermined time intervals *diastolic performance feedback loop*, and comprises a comparator, *pacing parameter optimization module* **124**, capable of comparing each of said time durations to an upper limit value to identify a first plurality of time durations above said upper limit value and

respective first magnitudes of respective deviations of said first plurality of time durations from said upper limit value, and a second plurality of time durations below said lower limit value and second magnitudes of deviations of said second plurality of time durations from said lower limit value, and comprises a memory in which said first plurality of time durations, said first magnitudes, said second plurality of time durations, and said second magnitudes are stored, *therapy history data* [0032 – 0033] (Fig. 1B).

With regard to **claim(s) 43 and 63,** Salo inherently discloses wherein said DHF determining device determines said time duration at a plurality of different times, *diastolic performance feedback loop*, and determines changes in the respective time durations determined at said different times, and comprises a memory in which said changes are stored, *therapy history data* [0032 – 0033, 0046].

Regarding **claim 47,** Salo discloses an implantable cardiac pacemaker comprising: a pulse generator, **114,** that emits stimulation pulses; an electrode system, **110A &110B**, adapted to interact with the heart of a subject to deliver said stimulation pulses to the heart in a pacing therapy regimen, a sensor adapted to interact with a heart to obtain information associated with functioning of the heart, **112 & 116**, and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration, of a predetermined phase of diastole of the heart; and a control unit, *pacing parameter optimization module* **124,** connected to said DHF determining device and to said pulse generator, said control device controlling said pulse generator to modify said pacing therapy regimen dependent on said DHF parameter (Abstract, Figs. 1A & 1B).

With regard to **claim(s) 34, 35, 39, 40, 55, 56, 60 and 61,** Salo discloses utilizing an acoustic sensor or accelerometer to determine a diastolic performance parameter upon which the blood flow velocity is based [0030 – 0031].

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claim(s) 44 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Salo et al. (US 2005/0102002, herein Salo)** in view of **Paul et al. (US 5,814,088, herein Paul)**.

Regarding **claim(s) 44 – 46,** Salo discloses all of the limitations as discloses above, but fails to disclose an alerting unit that emits a humanly perceptible alert.

However, Paul discloses an alerting unit that emits a humanly perceptible alert (Col. 2, Lines 13 – 32).

A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of utilizing an alerting unit to achieve notification of a patient of an alert situation. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Salo to include an alerting unit as taught by Paul, since notifying a patient of a problem can aid in the correction of that issue and potentially improve the patient's quality of life.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luther G. Behringer whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766